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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/982,616	10/17/2001	Frances E. Lund	AP33438 068443.0106	8224

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EXAMINER

BELYAVSKYI, MICHAIL A

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/982,616	Applicant(s) LUND ET AL.	
	Examiner Michail A Belyavskiy	Art Unit 1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-17, 20-23 and 25-34 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18, 19 and 24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Claims 1-34 are pending.

Applicant's election with traverse of group XIII, claims 18, 19 and 24 in response to restriction Requirement, filed 03/15/04 is acknowledged. Applicant traverse the Restriction Requirement on the grounds that claims of Groups VIII and XIII are conceptually linked and the search of Groups VIII and XIII together would not constitute a serious search burden on the examiner. This is not found persuasive because the MPEP 803 (August 2001) states that "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search". The Restriction Requirement enunciated in the previous Office Action meets this criteria and therefore establishes that serious burden is placed on the examiner by the examination of more than one Group. The Inventions are distinct for reasons elaborated in paragraphs 3-5 of the previous Office Action and above.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1-17, 20-23 and 25-34 are withdrawn from further consideration by the Examiner, 37 C.F.R. § 1.142(b) as being drawn to nonelected inventions.

Claims 18, 19 and 24 read on a method for identifying a compound that inhibits CD38 enzyme activity, wherein CD38 mediated cell migration is measured under consideration in the instant application.

2. The specification is objected to under 37 CFR 1.821(d) for failing to disclose SEQ ID NOS, for the nucleic acid sequence disclosed on page 73, paragraph 0151.

3. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention *to which the claims are directed*.

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4. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 19 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 19 and 24 are indefinite and ambiguous in being dependent upon non-elected claim 17.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 18 and 24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods for identifying a compound that inhibits CD38 enzyme activity comprising (i) contacting a cell expressing CD38 and chemoattractant receptors with a test compound in the presence of a chemoattractant and substrate and measuring the level of CD38 activity; (ii) in a separate experiment, contacting a cell expressing CD38 and chemoattractant receptors with a chemoattractant and substrate and measuring the level of CD38 activity, where the conditions are essentially the same as in part (i) and then (iii) comparing the level of CD38 activity measured in part (i) with the level of CD38 activity in part (ii), wherein a decrease level of CD38 activity in the presence of the test compound indicates that the test compound is a CD38 inhibitor does not reasonably provide enablement for methods for identifying a compound that inhibits CD38 enzyme activity comprising (i) contacting a cell expressing only CD38 with a test compound in the presence of a chemoattractant and substrate and measuring the level of CD38 activity; (ii) in a separate experiment, contacting a cell expressing only CD38 with a substrate and measuring the level of CD38 activity, where the conditions are essentially the same as in part (i) and then (iii) comparing the level of CD38 activity measured in part (i) with the level of CD38 activity in part (ii), wherein a decrease level of CD38 activity in the presence of the test compound indicates that the test compound is a CD38 inhibitor

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification does not enable one of skill in the art to practice the invention as claimed without undue experimentation.

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The Specification disclosed that the invention is based on the discovery that CD38 ADP-ribosyl cyclase activity is critically important in regulating neutrophil chemotaxis both in vivo and in vitro (see overlapping pages 14-15 in particular). The Specification also disclosed that in the claimed method for identifying a compound that inhibits CD38 enzyme activity, wherein CD38 mediated cell migration is measured it is essential that chemoattractants are included in steps (i) and (ii) (see page 37, paragraph 0083 in particular). Moreover, in Examples, disclosed in the specification on pages 57, 63 and 68 chemoattractants were included in both steps (i) and (ii). If the presence of chemoattractants is essential for methods for identifying a compound that inhibits CD38 enzyme activity wherein CD38 mediated cell migration is measured, than cells that expressing CD38 should also express a chemoattractant receptor. Based on the disclosure of the instant Specification and provided examples one skilled in the art would immediately understand that only cells expressing both CD38 and chemoattractant receptors are enabled to use in a methods for identifying a compound that inhibits CD38 enzyme activity, wherein CD38 mediated cell migration is measured, as claimed in claims 18 and 24.

8. No claim is allowed.

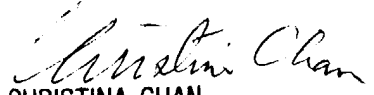
9. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. For example on page 16, paragraph 0035, the ATCC Deposit Number is missing. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michail Belyavskiy whose telephone number is 571/272-0840. The examiner can normally be reached Monday through Friday from 9:00 AM to 5:30 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571/272-0841.

The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michail Belyavskiy, Ph.D.
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Technology Center 1600
May 3, 2004


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